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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,728	12/28/2000	Akihiro Umezawa	766.43	6784

5514 7590 05/03/2005

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749,728

Applicant(s)

UMEZAWA ET AL.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-19,21-28,38,39,41,43,44,47-63 and 78-91 is/are pending in the application.
- 4a) Of the above claim(s) 47-63 and 78-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-19, 21-28, 38, 39, 41, 43, 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RD

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DETAILED ACTION

Please note that the Examiner of record and art unit has changed. The Examiner of record is now **Joseph T. Voitach** and the group art unit is now **1632**.

Applicants' amendment filed January 18, 2005 has been received and entered. The specification has been amended. Claims 2-5, 20, 29-37, 40, 42, 45, 46 and 64-77 have been cancelled. Claims 1, 6, 7, 43, 47, 52, 61, 78-86, 88, 90 and 91 have been amended. Claims 1, 6-19, 21-28, 38, 39, 41, 43, 44, 47-63, 78-91 are pending.

Election/Restriction

Claims 1, 6-19, 21-28, 38, 39, 41, 43, 44, 47-63, 78-91 are pending. Claims 47-63 and 78-91 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

This application contains claims 47-63 and 78-91, drawn to an invention nonelected with traverse in Paper No. 17. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-19, 21-28, 38, 39, 43 and 44 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated mouse stem cells isolated from an adult mouse bone marrow, wherein said mouse stem cell differentiates into a cardiomyocyte in the presence of a factor selected from the group consisting of 5-azacytidine, DMSO, PDGF, FGF-8, retinoic acid, ET-1, midkine, BMP4, NKX2.5/CSX and GATA4, and wherein said stem cell when transplanted in a mouse differentiates into cardiomyocyte or wherein said stem cell when transplanted into a mouse blastocyst differentiates into a cardiomyocyte, does not reasonably provide enablement for any other claimed embodiments is withdrawn.

Upon review of the teachings of the instant specification and the art of record, Examiner would agree that the guidance provided would not be limited to application in obtaining mouse bone marrow cells. The basis of the rejection set forth limitations reduced to practice in the instant specification, however the present claims simply set forth further characteristics of the claimed cell. The evidence of record indicates that a cell from the bone marrow is capable of serving as a pluripotent stem cell and is capable of differentiating into at least a cardiomyocyte. Whether a given cell meets the limitations of any specific claim would not require undue experimentation, only a simple characterization of any given cell such as the detection and presence of a cell surface marker.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, claim 1 has been amended to recite an "adult bone marrow-derived stem cell, wherein said stem cell can differentiate into at least two cells" however the specification fails to provide literal or figurative support for such a cell. The original claims as supported by the specification teach a stem cell isolated from the bone marrow which is multipotential capable of differentiating into any "adult tissues" (see for example claim 7). However, neither the specification nor the claims support a cell type that is derived and has the specific ability to differentiate into only at least two cells. Further, while dependent claims set forth specific markers and/or characteristics there is no unique nexus between these and the cell as claimed such that one would know that it is a stem cell with the claimed capabilities.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. Each of the specific markers or characteristics set forth in dependent claims are those of the cell isolated from bone marrow, not any derivation of such a cell. The claims are drawn to a product, and it would constitute undue experimentation to test the breadth of any potential isolated cell to see if it meets the requirements of the claims. Further, the simple limitations such as CD-34 positive fail to adequately define the cell, and fail

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to provide a nexus between such a marker and all the potential characteristics of a cell recited and encompassed by the claims.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claim 25 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

The evidence that FERM BP-7043 has been deposited under the Budapest Treaty and the declaration signed by the attorney have obviated the basis of the rejection.

Claims 29, 30 and 42 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

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Cancellation of the claims has obviated the basis of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Initially it is noted that amendments to the claims have addressed the basis of each the previous specific rejections.

Amended claim 1 is vague and indefinite in the recitation of “adult bone marrow-derived stem cell”. The metes and bounds of the claim are indefinite specifically with regards to the term “derived” because how similar or different the claimed cell is from the starting material, i.e. bone marrow, is not adequately set forth in the claim nor the specification.

Claims 6-19, 21-28, 38, 39, 41, 43 and 44 depend back to claim 1 or intervening claims, however as amended fail to provide adequate antecedent basis for “the cell” because claim 1 recites two cells a stem cell and at least two other cells including a cardiomyocyte, and clearly encompass other cell types as recited in dependent claims. More clearly setting forth the specific cell type in dependent claims would address the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Klug *et al.*

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Juttermann *et al.*

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand are rejected under 35 U.S.C. 102(b) as being anticipated by Shi *et al.*

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(a) as being anticipated by Young *et al.*

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(a) as being anticipated by Makino *et al.*

Applicants note the basis of the rejection, and argue that none of the cited references teach a bone-marrow derived stem cell that can differentiate into a cardiomyocyte and at least another cell type as required by the amended claims. See Applicants' amendment, pages 17-18, Applicants' arguments have been fully considered, but not found persuasive.

The 102 rejections are maintained for reasons of record because the invention as claimed only requires the cells "can differentiate" into different cell types. The amendment to the claims

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are noted, however the claims as amended are reasonably interpreted to be broad as they pertain to a product claim because the stem cell as claimed is "derived". There is no particular nor specific limitation to where the cell is obtained, if it meets the physical and/or functionally limitations encompassed by the claims. In this case, the cells taught by Klug *et al.*, Juttermann *et al.*, Shi *et al.*, Young *et al.*, and Makino *et al.* anticipate the claimed cell. For example, it is true the Klug *et al.* teach a embryonic stem cells, however stem cells can differentiate into cardiomyocytes and other cell types as required by amended claim 1, and are at least CD-34 positive (claim 9). Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Conclusion

No claim is allowed.

Claim 25 is objected to for being dependent on a rejected claim, however would be found allowable if rewritten in independent form.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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